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APR 24 2007

IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE

Serial No. : 10/054,300

Applicants : Takeshi IMANISHI et al.

Filed : January 22, 2002

For : NOVEL BICYCLONUCLEOSIDE  
ANALOGUES

Art Unit : 1623

Examiner : Traviss C. McIntosh III

Docket No. : 01834CIP/HG

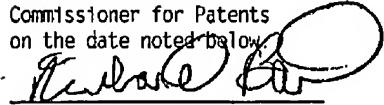
Confirm No. : 5360

Customer No.: 01933

REQUEST FOR RECONSIDERATION  
OF DECISION ON APPLICATION  
FOR PATENT TERM ADJUSTMENTCommissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450MAIL STOP PETITION

S I R :

This is a request for reconsideration of the DECISION ON  
APPLICATION FOR PATENT TERM ADJUSTMENT mailed April 10, 2007  
(hereinafter referred to as the "April 10, 2007 DECISION") which  
indicated a total PTA of 1033 days for the above-identified  
application.

CERTIFICATE OF FACSIMILE  
TRANSMISSION  
PTO NO. 1-571-273-8300TOTAL PAGES: 27 pages  
I hereby certify that this  
paper is being facsimile  
transmitted to the  
Commissioner for Patents  
on the date noted below.  
Attorney: Richard S. BarthDated: April 24, 2007

In the event that this Paper  
is late filed, and the  
necessary petition for  
extension of time is not filed  
concurrently herewith, please  
consider this as a Petition  
for the requisite extension of  
time, and to the extent not  
tendered by Form PTO-2038  
attached hereto, authorization to  
charge the extension fee,  
or any other fee required  
in connection with this  
Paper, to Account No. 06-1378.

A. Senior Petitions Attorney Nancy Johnson is thanked for her consideration of applicants' APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT INDICATED IN NOTICE OF ALLOWANCE (37 CFR §1.705) filed February 2, 2007.

Applicants are pleased that Ms. Johnson's April 10, 2007 DECISION granted applicants 1033 days of the 1119 days of PTA requested in applicants' aforesaid APPLICATION FOR PATENT TERM ADJUSTMENT filed February 2, 2007. However, for the reasons discussed hereinbelow, applicants respectfully request that they be granted an additional 86 days of PTA. Stated differently, applicants' respectfully request herein that they be afforded a total PTA of 1119 days, as requested in applicants' aforesaid APPLICATION FOR PATENT TERM ADJUSTMENT filed February 2, 2007.

B. Applicants respectfully disagree with the assessment of a 86 day applicant delay, as set forth on page 3, lines 9 to 27 of the April 10, 2007 DECISION, which is reproduced as follows:

"On January 6, 2004, at the request of the Office, applicants submitted a duplicate CRF of sequence listing<sup>2</sup>. By Notice mailed February 11, 2004, applicants were advised of omissions in this response. On April 1, 2004, applicants submitted a response correcting the omissions. Therein, applicants did not dispute the validity of the Office's assertion that

there were omissions in their response. In addition, it is specifically noted that the Statement under 37 CFR 1.821 provided was signed March 18, 2004. Thus, it was not a duplicate from the earliest filing. This further supports a conclusion that there were omissions in applicants' response as originally filed April 16, 2002 (and resubmitted January 6, 2004). Thus, a period of reduction of 86 days for the period beginning on the day after the date the reply having an omission was filed, January 7, 2004, and ending on the date that the reply or other paper correcting the omission was filed, April 1, 2004 is properly entered.

In view thereof, the correct determination of patent term adjustment at the time of the mailing of the Notice of Allowance is one thousand thirty-three (1033) days." (emphasis supplied)

The footnote 2 for the above quote reads as follows:

"<sup>2</sup> As shown in the record of the application, applicants' original response filed April 16, 2002 was damaged in the mail (and thus, was not received by the Office). Under the circumstances, it is appropriate to use the duplicate filed January 6, 2004 in ascertaining applicant delay pursuant to 1.704(c)(7)."

C. It is initially submitted that the "January 6, 2004" date set forth on page 3, lines 9 to 27 of the April 10, 2007 DECISION is incorrect. The duplicate CRF of the Sequence Listing was filed on January 26, 2004, as evidenced by the enclosed copy of the postcard receipt which was date stamped "JAN 26 2004" by the USPTO (see ATTACHMENT A hereto).

Accordingly, even assuming arguendo that there was an applicant delay due to the submission of the duplicate CRF of the Sequence Listing which was filed on January 26, 2004, the delay should be 66 days, not 86 days.

D. Applicants respectfully submit that for the following reasons the Sequence Listing submissions beginning on the aforesaid date of January 26, 2004 do not involve an "omission" in the context of 37 CFR 1.704(c)(7) (with reference to 37 CFR 1.135) and, therefore, should not result in a reduction of any days of PTA for the following reasons.

1. In response to a USPTO NOTICE TO FILE MISSING PARTS OF APPLICATION mailed March 25, 2002 (hereinafter referred to as the "March 25, 2002 NOTICE"), on April 16, 2002 , a SUBMISSION OF SEQUENCE LISTING (See ATTACHMENT B hereto) was mailed to the USPTO, which included (i) a computer readable form and a paper copy of the SEQUENCE LISTING and (ii) a STATEMENT UNDER 37 CR 1.821 of Takuo OKABE dated April 9, 2002 (hereinafter referred to as the "April 9, 2002 OKABE STATEMENT"). Enclosed herewith as ATTACHMENT C is the aforesaid paper copy of the SEQUENCE LISTING date stamped "APR 24 2002" by the USPTO. Enclosed herewith as ATTACHMENT D is the aforesaid STATEMENT UNDER 37 CFR 1.821 of Takuo OKABE dated April 9, 2002.

2. A copy of the Image File Wrapper for the above-identified application (enclosed herewith as ATTACHMENT E) evidences that the electronic file of this application includes said SEQUENCE LISTING and said STATEMENT UNDER 37 CFR 1.821 of Takuo OKABE dated April 9, 2002, as indicated by the following entries:

"04-24-2002 CRF Statement Paper and CRF are the same"

"04-24-2002 Sequence Listing."

3. Accordingly, the SEQUENCE LISTING and the April 9, 2002 OKABE STATEMENT filed on April 24, 2002 were a complete response (without any omissions) to the USPTO March 25, 2002 NOTICE.

4. The undersigned received a telephone call on January 23, 2004 from Ms. Nelson of OPIE, wherein Ms. Nelson requested that applicants provide a duplicate floppy disk of the computer readable form ("CRF") for the Sequence Listing that was filed on April 24, 2002. Ms. Nelson said that the original floppy disk of the CRF for the Sequence Listing was damaged during processing of the mail. Ms. Nelson did not request that a duplicate paper copy of the Sequence Listing be submitted. Ms. Nelson also did not request that a duplicate STATEMENT UNDER 37 CFR 1.821 be submitted.

5. On January 26, 2004, a paper entitled SUBMISSION OF DUPLICATE COPY OF COMPUTER READABLE FORM ("CRF") OF SEQUENCE LISTING was filed by applicants in the USPTO, together with a floppy disk of the Sequence Listing, which was a duplicate of the floppy disk that was earlier filed in the USPTO on April 24, 2002.

6. A USPTO NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES was mailed on February 11, 2004 (hereinafter referred to as the "February 11, 2004 NOTICE").

Said February 11, 2004 NOTICE had two requirements, which are reproduced below and identified as Paragraph No. 1 and Paragraph No. 2:

Paragraph No. 1:

"This application does not contain a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). Applicant must provide such statement. If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000)."

Paragraph No. 2:

"A copy of the 'Sequence Listing' in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up 'Raw Sequence Listing.' Applicant must provide a substitute computer readable form (CRF) copy of the 'Sequence Listing' and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d)."

The above Paragraph No. 2 of said February 11, 2004 NOTICE required the submission of a Substitute computer readable form of the Sequence Listing to correct errors indicated in a Raw Sequence Listing Error Report that was attached to said February 11, 2004 NOTICE.

7. DISCUSSION OF PARAGRAPH 2 OF THE FEBRUARY 11, 2004 NOTICE

A RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCES AND/OR AMINO ACID SEQUENCE DISCLOSURES was filed by the applicants on April 1, 2004 (hereinafter referred to as the "April 1, 2004 RESPONSE") (April 1, 2004 is the date that the 86 day applicant delay is set forth

on page 3 of the April 10, 2007 DECISION). Attached to said April 1, 2004 RESPONSE were a Substitute SEQUENCE LISTING (paper copy and a computer readable form thereof) and a STATEMENT UNDER 37 CFR 1.821(g) of Tomoki Echigo dated March 18, 2004 (hereinafter referred to as the "March 18, 2004 ECHIGO STATEMENT"), which was required only because a substitute Sequence Listing was filed.

The March 18, 2004 ECHIGO STATEMENT was filed in accordance with the 37 CFR 1.821 requirement that when a substitute Sequence Listing is filed, a new Statement Under 37 CFR 1.821 must also be filed.

The March 18, 2004 ECHIGO STATEMENT was not a duplicate of the April 9, 2002 OKABE STATEMENT, since the April 9, 2002 OKABE STATEMENT was for the original SEQUENCE LISTING filed on April 24, 2002, whereas the March 18, 2004 ECHIGO STATEMENT was for the Substitute SEQUENCE LISTING filed on April 1, 2004.

8. DISCUSSION OF PARAGRAPH NO. 1 OF THE FEBRUARY 11, 2004 NOTICE WHICH EXPLAINS THE REASONS WHY THE APRIL 1, 2004 RESPONSE DID NOT DISCUSS PARAGRAPH NO. 1 OF SAID FEBRUARY 11, 2004 NOTICE

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Paragraph No. 1 of said February 11, 2004 NOTICE starts out "This application does not contain a statement that the content of the sequence listing information recorded in computer readable form is identical to the written ... sequence listing...." This statement is clearly erroneous because the electronic file of the application does contain a Statement Under Rule 1.821 (the April 9, 2002 OKABE STATEMENT), which was filed on April 24, 2002, as explained in Paragraph Nos. D.1 and D.2 hereinbefore.

It is respectfully submitted that the April 10, 2007 DECISION, page 3, the first two sentences beginning with line 9, mischaracterized applicants' paper entitled "SUBMISSION OF DUPLICATE COPY OF COMPUTER READABLE FORM ("CRF") OF SEQUENCE LISTING" filed January 26, 2004 as a "response." Said filing of a floppy disk containing the Sequence Listing on January 26, 2004 was not a "response," but rather it was simply an accommodation to a telephone request of Ms. Nelson of the USPTO to file a duplicate copy of a floppy disk which was damaged while being processed. Ms. Nelson did not require a copy of the 37 CFR 1.821 Statement which was already of record. Accordingly, the

statement in the second sentence of the April 10, 2007 DECISION paragraph under discussion, stating that the NOTICE mailed February 11, 2004 advised applicants of "omissions" in a "response" is also a mischaracterization referring to the term "omission." Said first paragraph in the February 11, 2004 NOTICE is merely an erroneous statement that the application file did not include a Statement Under 37 CFR 1.821, when in fact it did include such Statement Under 37 CFR 1.821 (see the April 9, 2002 OKABE STATEMENT).

Since no "response" was filed on January 26, 2004, there cannot be an "omission" (see 37 CFR 1.135(c)).

When the undersigned was preparing the response to said February 11, 2004 NOTICE by submitting a Substitute Sequence Listing, together with the required Statement Under 37 CFR 1.821 for the Substitute Sequence Listing, the undersigned considered that the erroneous statement in Paragraph No. 1 of the February 11, 2004 NOTICE (that the application file did not include a Statement Under 37 CFR 1.821) was moot because the April 1, 2004 submission in response to the requirement of Paragraph No. 2 included a new Statement Under 37 CFR 1.821 (the March 18, 2004 ECHIGO STATEMENT) which was required only because of the filing of a Substitute Sequence Listing on April 1, 2004.

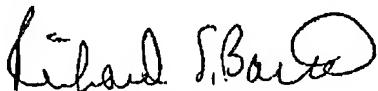
It is respectfully submitted that the filing on April 1, 2004 of the Substitute Sequence Listing and the new Statement Under 37 CFR 1.821 (the March 18, 2004 ECHIGO STATEMENT) resulted in meeting all of the USPTO requirements relating to the filing of a Substitute Sequence Listing, and that the original Sequence Listing papers filed April 24, 2002 completely satisfied all of the initial requirements for filing a Sequence Listing and the corresponding Statement Under 37 CFR 1.821 (the April 9, 2002 OKABE STATEMENT), and that it was not incumbent upon the applicants to inform the USPTO that the application file correctly reflected the foregoing.

E. In conclusion, it is respectfully submitted that applicants should not be penalized with a loss of PTA because the floppy disk that the applicants filed on April 16, 2002 was damaged during processing and because applicants assisted the USPTO in providing a duplicate of the aforesaid floppy disk.

F. In view of the above, it is respectfully requested that the patent term adjustment for the above-identified application be changed to 1119 days (USPTO delay of 1119 days; applicant delay of 0 days).

If any fees are required, authorization is given to charge such fees to Deposit Account No. 06-1378.

Respectfully submitted,



RICHARD S. BARTH  
REG. NO. 28,180

FRISHAUF, HOLTZ, GOODMAN & CHICK, P.C.  
220 FIFTH AVENUE, 16th FLOOR  
NEW YORK, NEW YORK 10001-7708  
Tel. Nos. (212) 319-4900  
             (212) 319-4551/Ext. 219  
Fax No. (212) 319-5101  
E-Mail Address: BARTH@FHGC-LAW.COM  
RSB/ddf

- Encs.: (1) a copy of postcard receipt dated January 26, 2004  
(ATTACHMENT A)
- (2) a copy of SUBMISSION OF SEQUENCE LISTING dated April 16, 2002 (ATTACHMENT B)
- (3) a copy of SEQUENCE LISTING (8 pages) date stamped "APR 24 2002" (ATTACHMENT C)
- (4) a copy of STATEMENT UNDER 37 CFR 1.821 of Takuo OKABE dated April 9, 2002 (ATTACHMENT D)
- (5) a copy of the USPTO Image File Wrapper for the above-identified application (ATTACHMENT E)

ATTACHMENT A

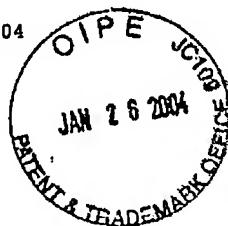
0104 Rec'd PCT/PTO 26 JAN 2004

Attorney Docket: 01834CIP/HG  
Serial No.: 10/054,300  
Applicants: Takeshi IMANISHI et al.  
Filed : January 22, 2002

RECEIPT ACKNOWLEDGED: SUBMISSION OF DUPLICATE COPY OF  
COMPUTER READABLE FORM ("CRF") OF SEQUENCE LISTING (disk).

EXPRESS LABEL EV 395 877 142 US  
DATE OF DEPOSIT: January 26, 2004

RSB/ddf



ATTACHMENT BAttorney Docket: 01834CIP/HGIN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE

Applicant(s): Takeshi IMANISHI et al.

Serial No. : 10/054,300

Filed : January 22, 2002

For : NOVEL BICYCLONUCLEOSIDE  
ANALOGUES

Art Unit : 1646

Examiner :

SUBMISSION OF SEQUENCE LISTINGCommissioner for Patents  
Washington, D.C. 20231

S I R :

The NOTICE TO FILE MISSING PARTS OF APPLICATION - Filing Date Granted dated March 25, 2002 (copy enclosed) specified that a Statement Under 37 CFR 1.821 and a computer readable form of the Sequence Listing were required and that they be filed within two months from March 25, 2002, the mailing date of said NOTICE.

Submitted concomitantly herewith are the following:

- (1) a computer readable form and a paper copy of the Sequence Listing, and
- (2) a STATEMENT UNDER 37 CFR 1.821 of Mr. Takuo Okabe, dated April 9, 2002.

CERTIFICATE OF MAILING

I hereby certify this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class mail in an envelope addressed to:  
Commissioner for Patents,  
Washington, D.C. 20231 on the date noted below.

Attorney: Richard S. Barth

Dated: April 16, 2002

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper, to Account No. 06-1378.

A PRELIMINARY AMENDMENT is being submitted concomitantly herewith to replace the SEQUENCE LISTING in the originally filed application with the SEQUENCE LISTING which is being submitted herewith.

It is respectfully submitted that the application complies with all the requirements of 37 CFR 1.821 to 1.825.

Respectfully submitted,



Richard S. Barth  
Reg. No. 28,180

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767 THIRD AVENUE - 25TH FLOOR  
NEW YORK, NEW YORK 10017-2023  
Tel. No. (212) 319-4900  
Fax No. (212) 319-5101  
RSB/ddf

- Enclosures: (1) A copy of the USPTO NOTICE dated March 25, 2002
- (2) Computer readable form (disk) and paper copy of the Sequence Listing
- (3) STATEMENT UNDER 37 CFR 1.821 of Mr. Takuo Okabe dated April 9, 2002
- (4) PRELIMINARY AMENDMENT

ATTACHMENT C

## SEQUENCE LISTING

&lt;110&gt;Imanishi, Takeshi

Obika, Satoshi

&lt;120&gt;Novel Bicyclo[nucleoside Analogues

&lt;130&gt;01834CIP/HG

&lt;140&gt;US 10/054,300

&lt;141&gt;2002-01-22

&lt;150&gt;JP HEI11-207170

&lt;151&gt;1999-07-22

&lt;160&gt;6

&lt;170&gt;PatentIn Ver.2.0

&lt;210&gt;1

&lt;211&gt;12

&lt;212&gt;DNA

&lt;213&gt;Artificial Sequence

&lt;220&gt;

<223> Description of Artificial Sequence: Synthesized  
oligonucleotide for testing the nuclease  
resistance

&lt;220&gt;

&lt;221&gt;modified\_base

&lt;222&gt;(11)

&lt;223&gt;modified uridine

&lt;400&gt;1

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12

<210>2

<211>15

<212>DNA

<213>Artificial Sequence

<220>

<223>Description of Artificial Sequence: Synthesized  
oligonucleotide for testing the formability of a  
triple strand

<220>

<221>modified\_base

<222>(6)

<223>5-methyl 2'-deoxycytidine

<220>

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<222>(10)

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<220>

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<222>(14)

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<400>2

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<210>3

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<212>DNA

<213>Artificial Sequence

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oligonucleotide for testing the formability of a  
triple strand

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21

<210>4

<211>21

<212>DNA

<213>Artificial Sequence

<220>

<223>Description of Artificial Sequence: Synthesized  
oligonucleotide for testing the formability of a  
triple strand

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21

<210>5

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<212>DNA

<213>Artificial Sequence

&lt;220&gt;

<223>Description of Artificial Sequence: Synthesized oligonucleotide for testing the formability of a triple strand

&lt;220&gt;

&lt;221&gt;modified\_base

&lt;222&gt;(6)

&lt;223&gt;5-methyl 2'-deoxycytidine

&lt;220&gt;

&lt;221&gt;modified\_base

&lt;222&gt;(10)

&lt;223&gt;5-methyl 2'-deoxycytidine

&lt;220&gt;

&lt;221&gt;modified\_base

&lt;222&gt;(12)

&lt;223&gt;5-methyl 2'-deoxycytidine

&lt;220&gt;

&lt;221&gt;modified\_base

&lt;222&gt;(14)

&lt;223&gt;5-methyl 2'-deoxycytidine

&lt;400&gt;5

ttttnttn tntnt

15

&lt;210&gt;6

&lt;211&gt;12

&lt;212&gt;DNA

&lt;213&gt;Artificial Sequence

&lt;220&gt;

<223>Description of Artificial Sequence: Synthesized oligonucleotide for testing the nuclease

resistance

<400>6

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12

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<212> DNA

<213> Artificial Sequence

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<223> Description of Artificial Sequence: Synthesized  
oligonucleotide for testing the formability of a  
triple strand

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4'-C-methylene-5-methyluridine

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4'-C-methylene-5-methyluridine

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4'-C-methylene-5-methyluridine

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<212> DNA

<213> Artificial Sequence

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<223> Description of Artificial Sequence: Synthesized  
oligonucleotide for testing the formability of a  
triple strand

&lt;220&gt;

&lt;221&gt; modified\_base

&lt;222&gt; (1)

&lt;223&gt; 3'-amino-3'-deoxy-2'-O,

4'-C-methylene-5'-methyluridine

&lt;220&gt;

&lt;221&gt; modified\_base

&lt;222&gt; (3)

&lt;223&gt; 3'-amino-3'-deoxy-2'-O,

4'-C-methylene-5'-methyluridine

&lt;220&gt;

&lt;221&gt; modified\_base

&lt;222&gt; (5)

&lt;223&gt; 3'-amino-3'-deoxy-2'-O,

4'-C-methylene-5'-methyluridine

&lt;220&gt;

&lt;221&gt; modified\_base

&lt;222&gt; (7)

&lt;223&gt; 3'-amino-3'-deoxy-2'-O,

4'-C-methylene-5'-methyluridine

&lt;220&gt;

&lt;221&gt; modified\_base

&lt;222&gt; (9)

&lt;223&gt; 3'-amino-3'-deoxy-2'-O,

4'-C-methylene-5'-methyluridine

&lt;400&gt;

ntntntntnt

10

&lt;210&gt; 9

&lt;211&gt; 10

&lt;212&gt; DNA

&lt;213&gt; Artificial Sequence

&lt;220&gt;

<223> Description of Artificial Sequence: Synthesized  
    oligonucleotide for testing the formability of a  
    triple strand

&lt;220&gt;

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<222> (2)  
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      4'-C-methylene-5-methyluridine  
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      4'-C-methylene-5-methyluridine  
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      4'-C-methylene-5-methyluridine  
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ATTACHMENT DAttorney Docket: 01934CIP/HGIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Takeshi IMANISHI et al.  
Serial No. : 10/054,300  
Filed : January 22, 2002  
For : NOVEL BICYCLONUCLEOSIDE  
ANALOGUES  
  
Art Unit :  
Examiner :

STATEMENT UNDER 37 CFR 1.821

Assistant Commissioner for Patents  
Washington, D.C. 20231

S I R :

The below-named person hereby states that:

The Sequence Listing recorded on the enclosed computer  
readable form (disk) is identical to the written Sequence  
Listing (printout) annexed hereto (i.e., the content of the paper  
copy and computer readable copy submitted herewith are the same),  
and the sequences in said Sequence Listing are identical to the  
sequences filed with the above-referenced patent application. No  
new matter has been added.

Date: April 9, 2002

Takuo Okabe  
Name: Takuo OKABE

ATTACHMENT E

10/054,300 NOVEL BICYCLONUCLEOSIDE ANALOGUES

01-31-  
2007::12:04:51

This application is officially maintained in electronic form. To View: Click the desired Document Description. To Download and Print: Check the desired document(s) and click Start Download.

**Available Documents**

Mail Room Date	Document Description	Document Category	Page Count
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01-04-2007	Notice of Allowance and Fees Due (PTOL-85)	PROSECUTION	4
01-04-2007	List of References cited by applicant and considered by examiner	PROSECUTION	11
01-04-2007	Issue Information including classification, examiner, name, claim, renumbering, etc.	PROSECUTION	1
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